

## REMARKS

Reconsideration and withdrawal of the claim rejections are requested in view of the amendments and remarks herein.

### **I. STATUS OF CLAIMS AND FORMAL MATTERS**

Claims 9, 10, 12, 13 and 25 are under consideration in this application. Claims 9, 10, 12 and 13 have been amended; claim 25 has been added. Support for the amended claims is found throughout the specification. Specifically, support for the amendments to claim 9 can be found in original claims 1 and 4. Support for the amendments to claim 10 can be found in original claims 2 and 4. Recitation of "hybridizes under stringent conditions" in claim 10 can be found in the paragraph bridging pages 11 and 12 of the application. Support for new claim 25 can be found in original claim 3. No new matter is added.

The objections to claims 9, 10, 12 and 13 have been obviated by the instant amendment.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims were in full compliance with the requirements of 35 U.S.C. §112. The amendments of and additions to the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Furthermore, it is explicitly stated that the herewith amendments should not give rise to any estoppel, as the herewith amendments are not narrowing amendments.

### **II. THE REJECTIONS UNDER 35 U.S.C. §112, 1<sup>ST</sup> PARAGRAPH ARE OVERCOME**

#### **The Application Contains Adequate Written Description**

Claims 9, 10, 12 and 13 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking adequate written description. The rejection is traversed.

Claims 9 and 10 have been amended such that the claimed polynucleotide encodes a polypeptide of known (and recited) structure and function. For example, the structure of the polypeptide in claim 9 is given by both the molecular weight and the amino acid sequence, and its function is clearly recited in part (b) of claim 9.

Similarly, the claimed polynucleotide of claim 10 and the polypeptide it encodes are described functionally and structurally by sequence identifiers and hybridization conditions.

Hybridization techniques using a known nucleotide sequence (*e.g.* SEQ ID NO: 6) as a probe under stringent conditions were conventional in the art at the time of filing. A person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the stringent hybridization conditions set forth in the claim yield structurally similar polynucleotides. Therefore, a representative number of species is disclosed, and claim 10, drawn to a genus of nucleic acids that hybridize with a given sequence and encode a protein with a specific activity, is adequately described. (See Example 9 of the USPTO's "Synopsis of Application of Written Description Guidelines".)

With respect to the inclusion of variants of SEQ ID NO:7 in part (a) of claim 10, the paragraphs beginning on page 7, line 7, of the specification define and discuss what is meant by "functionally equivalent variants". It is reasonable to assume that such functionally equivalent polypeptides will exist, and the specification provides methods for producing (page 8, lines 4-27) and testing the function of (page 19, lines 9-31) such polypeptides. By analogy with chemical cases, the applicant should be entitled to claim not only the specific, isolated polypeptide, but also those variants that can be reasonably predicted to have the same activity.

#### **The Claims Are Enabled**

Claims 9, 10, 12 and 13 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. The rejection is traversed.

The Office Action admits that the specification is enabling for DNA of SEQ ID NO:6; however, it alleges that "[t]he claims are drawn to DNA fragments of SEQ ID NO:6 having unlimited structure encoding a polypeptide with no or unknown activity." This is not the case. As discussed above, claims 9 and 10 contain structural and functional limitations that clearly define members of the claimed genus. Further, the application contains specific teaching regarding how to isolate and identify the claimed polynucleotides. (See, for example, page 8, line 29, through page 12, line 2.) All of the guidance required in order for the skilled artisan to make and use the claimed polynucleotides is present in the application.

Therefore, in view of the *Wands* factors, as listed on page 5 of the Office Action, the claims are enabled: the quantity of experimentation is not undue, a high amount of direction is provided, particularly in the form of working examples, the nature and state of the art are predictable and well-developed, and the relative skill of those in the art is high. All of these factors justify the breadth of the claims.

In view of the foregoing, it is submitted that the claims are in compliance with the first paragraph of §112, and reconsideration and withdrawal of the rejections thereunder are requested.

**III. THE REJECTION UNDER 35 U.S.C. §102 ARE OVERCOME**

Claims 10, 12 and 13 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Pannetier *et al.* The rejection is traversed.

Contrary to the assertions in the Office Action, Pannetier does not teach or suggest the claimed invention. Pannetier relates to techniques for the *in vitro* amplification of uncharacterized enzymes. A polynucleotide encoding a polypeptide with functional activity as a serine protease inhibitor or a divalent cation binding agent is neither taught nor suggested by Pannetier. Furthermore, the Examiner has not provided any sequence comparison or even an explanation that shows how SEQ ID NO:23 of Pannetier is a variant of SEQ ID NO:6 of the instant invention.

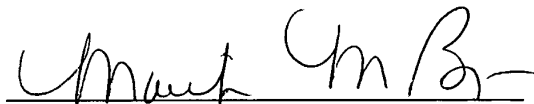
Therefore, the claims are not anticipated by Pannetier, and reconsideration and withdrawal of the §102 rejection are requested.

**CONCLUSION**

In view of the remarks and amendments herewith, it is believed that the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP  
Attorneys for Applicant



By: Marilyn Matthes Brogan  
Reg. No. 31,223  
Tel: (212) 588-0800